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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yasuyoshi Ueda

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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

11/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,669	Applicant(s) UEDA ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/02/09, 06/03/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Receipt of Applicants response and claim amendments filed on 07/27/09 are acknowledged. Receipt of IDS's filed on 11/02/09 and 06/03/09 are also acknowledged. Claims 1-25 and 28-30 are pending. Claims 28-30 have been newly added. Claims 1-14, and 17-20 remain withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 15, 16, 21-25 and 28-30 are examined on the merits.

NEW REJECTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15, 21-22 and 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (i.e. naturally occurring). The instant claim 15 is directed to a process for producing a ubiquinol-enriched oil/fat-containing food product for human ingestion which comprises adding ubiquinol together with an emulsifier and/or an oil/fat containing food ingredient to a human food material wherein the oil/fat has a melting point of not lower than 20 degrees C which reads on raising pork. When a pig is born and grows it produces a ubiquinol-enriched oil/fat-containing food product for human ingestion and also naturally contains lard (as evidenced by Kubo et al (2008) and wikipedia (see cited as interest)). As evidenced by

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Kubo et al 63 naturally occurring food items such as pork are naturally ubiquinol-enriched (abstract, Tables 1-3). According to Table 3 pork shoulder contains 56.4% ubiquinol and a ratio of 25.4/19.6 of ubiquinol/ubiquinone and contains 40 micrograms/gram of ubiquinol/ubiquinone and as evidenced by wikipedia pork contains lard and comes from any part of the pig (pgs. 1-2), which meets the limitations of claims 15, 21-22 and 30. Thus the process as instant claimed given the broadest reasonable interpretation reads on the natural process of a pig as it grows produces a ubiquinol-enriched oil/fat-containing food product for human ingestion and contains lard (a solid fat at 20 degrees C) as evidenced by the cited references.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 23-25 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Chopra (US 6,441,050).

The instant claims are drawn to a process for producing a ubiquinol-enriched oil/fat-containing food product for human ingestion which comprises adding ubiquinol

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together with an emulsifier and/or an oil/fat containing food ingredient to a human food material wherein the oil/fat has a melting point of not lower than 20 degrees C.

It is noted that the Examiner is interpreting the instant claim as "wherein [if present] the oil/fat has a melting point of not lower than 20 degrees", since the oil/fat is not required due to the "and/or" statement which reads optionally.

- Chopra teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together with polysorbate and/or sorbitan fatty acid ester (SpanTM) emulsifiers, lecithin, triglycerides/oil (such as tallow, lard, etc (which are solid oils at room temperature; see wikipedia cited as interest, pg. 2)) and a sweetener (i.e. ordinary human food/confection) (abstract, col. 8, lines 5-14; col. 3, line 45-col. 4, line 67, claim 1). According to the instant specification (PGpub, [0092]) emulsifiers include sorbitan fatty acid esters and lecithin, thus meeting the limitations of instant claims 15 and 24.
- The emulsifiers polysorbate and SpanTM are present from 0.1-35%, preferably 1.5-25% and the triglyceride/oil component which includes hydrogenated vegetable oils, tallow, lard, stearin, etc present from 0.2-50% which reads on the oil/fat content of not less than 0.5% (abstract, claim 1) (meeting the limitations of instant claims 23).
- The ubiquinol is added to the oil/fat then heated and lastly added to the sweetener (col. 9 lines 45-55; col. 11, lines) (according to the limitations of instant claims 15 and 25).

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- Chopra teaches that the composition is removed from heat and mixed while cooled (col. 11, lines 51-54) (meeting the limitations of instant claim 28).
- The formulation is preferably a ubiquinol-oil emulsion according to Chopra (col. 5, lines 48-55; col. 7, lines 13-15) (meeting the limitations of instant claim 29).
- A syrup product is taught in Example 1 (meeting the limitations of instant claim 30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (US 6,441,050).

- Chopra is taught above and teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together with an emulsifier, oil such as lard and a sweetener (i.e. ordinary human food/confection).
- Chopra further teaches that the ubiquinone is converted into ubiquinol by the addition of a reducing agent. See e.g. col. 10 lines 14-20.

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- The ratio of ubiquinol/ubiquinone (instant claim 21) is not explicitly mentioned, nor is the percent of the composition as ubiquinone (instant claim 22), however, given that the ubiquinone is converted to ubiquinol, it is the Examiners belief that the ubiquinone will be less than 50% by weight after conversion, and specifically between the range of 0.0001 to 50%. Instant claims 21 and 22.
- Regarding claim 16, the purity of ubiquinol is not explicitly mentioned in the reference; however, a purity of greater than 0.01% is a large range that the Examiner believes would cover the ubiquinol used in Chopra. Furthermore, the large range claimed demonstrates that a specific purity is not of significance and it is believed that anytime a reference specifically mentions "ubiquinol" the purity will far exceed 0.01%, especially after conversion of ubiquinone to ubiquinol as taught by Chopra.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make a process for producing ubiquinol-enriched oil/fat containing foods comprising adding the ubiquinol and ubiquinone together with an oil/fat containing food to a sweetener/food material at elevated temperature, as taught by Chopra. There is motivation to have ubiquinone in a lower ratio or proportion because Chopra teaches converting a portion of ubiquinone to ubiquinol. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Cited As Interest

Lard definition from Wikipedia (<http://en.wikipedia.org/wiki/Lard>) has a melting point of 30-48 degrees C depending on the area of the pig that it is that it is from (i.e. backfat is 30-40 degrees C) (pg. 2).

Response to Arguments

Applicant's arguments with respect to claims 15-16, 21-25 and newly added claims 28-30 have been considered but are not persuasive and moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the prior art Chopra does not teach an "oil/fat having a melting point of not lower than 20 degrees C." Firstly, the Examiner respectfully points out that "an oil/fat having a melting point of not lower than 20" is not a required part of instant independent claim 15, it is merely optional as the instant claim read "and/or". Chopra teaches emulsifiers such as SpanTM and lecithin and thus anticipates claim 15, 25 and 28-30. Further, Applicant argues that the products claimed in instant claim 24 are not taught however Chopra teaches making a sugar/flavored syrup, suspension, elixirs, etc or liquid product for children to orally ingest (Example 1; col. 1, lines 11-18) which anticipates confections, sauces, liquors and/or beverage instant claimed in claim 24. Chopra also teaches that triglycerides and vegetable oil are used interchangeably in the patent and that triglycerides/vegetable oils include hydrogenated oils, tallow, lard, stearin, etc which are all solid fats and have a "melting point of not lower than 20 degrees C" in amounts of 0.2-50% (and cited as interest shows that lard specifically has a melting point of 30-48

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degrees C) (col. 7, lines 40-42 and 49-51; col. 8, lines 5-10, claim 1). As such the prior art clearly anticipates an oil/fat component with a “melting point of not lower than 20 degrees C” and applicants arguments are not persuasive. Applicant also argues that the prior art does not teach the newly added claims processes, however as detailed above Chopra does indeed teach heat, mixing, cooling while mixing the composition, and emulsion formulations.

Conclusions

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06/03/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/B. B./
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615